UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MARIA GIOIA,	:	
	:	
Plaintiff,	:	**2:19-cv-04629-JMA-SIL**
	:	
-against-	:	**2:19-cv-05377-JMA-SIL**
	:	
JANSSEN PHARMACEUTICALS,	:	
	:	
Defendant.	:	
	:	
	:	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT JANSSEN PHARMACEUTICALS, INC.'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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Defendant Janssen Pharmaceuticals, Inc. ("Janssen"), by and through its undersigned counsel and pursuant to Federal Rule of Civil Procedure 12(b)(6), hereby submits this memorandum of law in support of its Motion to Dismiss for failure to state a claim upon which relief can be granted.[1]

PRELIMINARY STATEMENT

Plaintiff Maria Gioia seeks to recover damages for side effects she claims to have suffered from a U.S. Food and Drug Administration ("FDA") approved medication, Invega®. Invega® is an indicated treatment for schizophrenia and schizoaffective disorder and was approved by the FDA on December 19, 2006. Plaintiff's complaint does not specifically indicate what side-effects Plaintiff claims to have experienced, merely indicating that the side-effects and "ultimate outcome" caused her to lose a career as a primary care physician.

Plaintiff appears to be bringing two causes of action: lack of informed consent and failure to warn. Plaintiff's lack of informed consent claim must be dismissed because it is a type of medical malpractice claim and is not a cognizable cause of action against a pharmaceutical manufacturer such as Janssen. In addition, Plaintiff's failure-to-warn claim must be dismissed because she has not pled enough facts to state a claim to relief that is plausible on its face.

PROCEDURAL HISTORY AND BACKGROUND

I. PROCEDURAL HISTORY

Plaintiff commenced her first action by serving Janssen with a state court summons with notice on August 7, 2019. Janssen removed that action (*Gioia I*, 2:19-cv-04629-JMA-SIL) to this Court on August 12, 2019 and filed an answer, denying all liability. *See* Gioia

[1] Janssen brings this motion in *Gioia I*, 2:19-cv-04629-JMA-SIL and *Gioia II*, 2:19-cv-05377-JMA-SIL.

I, Dkt. Nos. 1, 3. Janssen subsequently advised Plaintiff that her summons with notice failed to comport with federal pleading standards and that, if Plaintiff failed to file an amended complaint within thirty (30) days, Janssen would move to dismiss.[2] *See* Russo Decl., Ex. A. After receiving Janssen's correspondence, Plaintiff served an affidavit on Janssen, suggesting that she had not actually filed the lawsuit that she had served. *See* Russo Decl., Ex. B.

Plaintiff did not amend her complaint, but instead filed a separate lawsuit against Janssen in New York Supreme Court, Suffolk County, on August 29, 2019. Janssen timely removed that action (*Gioia II*, 2:19-cv-05377-JMA-SIL) to this Court on September 20, 2019. *See* Gioia II, Dkt. No. 1. Janssen again advised Plaintiff that if she did not file an amended complaint, it would move to dismiss it. *See* Russo Decl., Ex. C.

Although Plaintiff does not actually plead any causes of action, Janssen construes her complaints to allege primarily that she was injured as a result of Janssen's failure to warn about the possible side effects associated with Invega®. Specifically, Plaintiff alleges that the nature of this action is "Misinformation leading to end of [her] career as a primary care physician. . . Invega.com." *Gioia I*, Dkt. No. 1-1 (Compl.) at 2; *see also Gioia II*, Compl. at 2 (stating that she is suing Janssen "for loss of career as primary care physician due to no informed consent or warnings of Invega ultimate outcome and side effects.").[3] In addition, Janssen construes her complaints to be asserting a non-cognizable "lack of informed consent" claim.

Plaintiff does not identify in any of her filings: (i) the physician that prescribed the medication she purportedly took, (ii) the purpose for which the medication was prescribed,

[2] Janssen also provided Plaintiff with a copy of Rule 8 of the Federal Rules of Civil Procedure and the United States Supreme Court's decision in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

[3] In an email attached to her summons with notice, Plaintiff lists a litany of conditions from which she purportedly suffered. Among other things, Plaintiff claims to have suffered hypothyroidism, nerve damage, motor and vocal tics, confusion, and "metabolic syndrome[s]," including hypertension, diabetes, and stroke. *Id*. at 6-7. The second complaint does not specify, however, what injuries Plaintiff allegedly suffered. *See* Gioia II, Dkt. No. 1-1 (Compl.)

(iii) the date(s) on which she ingested the medication or (iv) when she suffered the alleged injuries. *See generally* Compls. Nor does Plaintiff specify what "misinformation" Janssen allegedly provided, when, and to whom. *Id.*

II. INVEGA® APPROVAL AND LABELING

Invega® is an indicated treatment for schizophrenia and was approved by the FDA on December 19, 2006. *See* Russo Decl., Ex. D.[4] At the time Invega®'s was first marketed in the United States, the FDA approved package insert contained a number of warnings and precautions. The warnings included: QT prolongation (cardiac arrest), neuroleptic malignant syndrome, tardive dyskinesia (involuntary nerve movements), hyperglycemia and diabetes mellitus (metabolic changes), gastrointestinal obstruction, and cerebrovascular adverse events (including stroke). *See id.*, Ex. E at 6-10. The package insert also described the following precautions and possible side effects: orthostatic hypotension and syncope, seizures, dysphagia, suicide, cognitive and motor impairment, priapism, thrombotic thrombocytopenia purpura, issues with body temperature regulation, antiemetic effects, cardiac disorders, nervous system disorders and hypertension. *See id.*, Ex. E at 10-13. Thus, the symptoms that Plaintiff claims to have suffered, including: motor and vocal tics,[5] hypertension, diabetes, and stroke, have all appeared in the package insert from the date of Invega®'s FDA approval.

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[4] The Court may take judicial notice of the FDA approval of Invega® and the FDA approved package insert. *See Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) (taking judicial notice of FDA's approval "based on FDA public records available at [FDA's website]"); *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) (taking judicial notice of FDA documents and noting that in deciding a motion to dismiss "[p]ublic documents issued by government agencies such as the Food and Drug Administration ("FDA") may also be considered.")

[5] As discussed *supra*, the 2006 FDA approved package insert for Invega® included a warning for tardive dyskinesia. As explained in the package insert, tardive dyskinesia is "[a] syndrome of potentially irreversible, involuntary, dyskinetic movements." *See* Russo Decl., Ex. E at 8. "Tics" are dyskinetic movements. *See* University of Arkansas, *Glossary of Movement Disorder Terms*, available at: https://neurology.uams.edu/neurology-clinical-services/movement-disorders/glossary-of-movement-disorder-terms/#Tardive%20Dyskinesia (last visited Jan. 31, 2020) (defining tardive dyskinesia and tics).

LEGAL STANDARD

When evaluating a Fed. R. Civ. P. 12(b)(6) motion, the Court must construe the Complaint in the light most favorable to the plaintiff. *Gant v. Wallingford Bd. of Educ.*, 69 F.3d 669, 671 (2d Cir. 1995). However, the Court "need not assume the truth of conclusions of law or unwarranted factual inferences." *Delta Air Lines v. Kramarsky*, 650 F.2d 1287, 1298 (2d Cir. 1981).

To survive a Rule 12(b)(6) motion, a plaintiff must plead in her complaint "enough facts to state a claim to relief that is *plausible on its face*." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) (emphasis added). To state a "plausible" claim, a plaintiff must plead "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rather, a complaint must include sufficient "*factual content* that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (emphasis added). While a complaint does not require "detailed factual allegations," the "factual allegations must be enough to raise a right to relief above the speculative level"; allegations setting forth claims that are merely "conceivable" are insufficient. *Twombly*, 550 U.S. at 555. If a plaintiff fails to "nudge[] their claims across the line from conceivable to plausible, their complaint must be dismissed." *Id.* at 570.

Although the Court is "obligated to construe a *pro se* complaint liberally," *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009), "the liberal pleading standard accorded to *pro se* litigants is not without limits." *Garcia v. Falk*, No. 09-cv-2045 (DLI)(LB), 2015 U.S. Dist. LEXIS 40960, at *10 (E.D.N.Y. Mar. 30, 2015). Even "a [*pro se*] complaint must plead sufficient facts to 'state a claim to relief that is *plausible* on its face.'" *Caldwell v. Pesce*, 83 F. Supp. 3d 472, 480 (E.D.N.Y. 2015), *aff'd*, 639 F. App'x 38 (2d Cir. 2016) (quoting *Twombly*, 550 U.S. at 570 (emphasis added).) Plaintiff cannot meet this standard.

ARGUMENT

I. PLAINTIFF'S LACK OF INFORMED CONSENT CLAIM MUST BE DISMISSED BECAUSE IT IS NOT A COGNIZABLE CLAIM AGAINST A PHARMACEUTICAL MANUFACTURER

To establish a lack of informed consent claim under New York law, Plaintiff must prove "that the *person providing the professional treatment* failed to disclose alternatives thereto and failed to inform the patient of reasonably foreseeable risks associated with the treatment, and the alternatives, that a *reasonable medical practitioner* would have disclosed in the same circumstances." *Spano v. Bertocci*, 299 A.D.2d 335, 337-38 (2d Dep't 2002) (emphasis added). As Plaintiff admits, Janssen is a pharmaceutical manufacturer, not a medical provider. *Gioia II*, ECF Dkt. No. 15 at 28 ("Janssen Pharmaceuticals, makers of Invega"). Thus, a lack of informed consent claim is not a cognizable claim against Janssen and must be dismissed.

The reason a lack of informed consent is not a cognizable claim against a pharmaceutical manufacturer is because under New York's learned intermediary doctrine, the duty pharmaceutical manufacturers owe is to the medical professional prescribing the medicine, not the patient. *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999) (noting that a pharmaceutical manufacturer's "duty is fulfilled by giving adequate warning to the prescribing physician."). As the New York Court of Appeals explained, "[w]arnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects." *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993). This is because "[t]he physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Id.* Put differently, New York law places the duty to warn patients of potential risks attendant to a course of treatment on the patient's doctor,

who is best able to evaluate the risks and benefits for a particular patient. *See, e.g.*, *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980) ("The doctor acts as an 'informed intermediary' between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use."); *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61 (4th Dep't 1979) ("[T]he physician's function is to evaluate a patient's needs, assess the risks and benefits of available drugs and then prescribe a drug, advising the patient of its risks and possible side effects."). Thus, Plaintiff's assertion of a lack of informed consent claim against a pharmaceutical manufacturer also must be dismissed because Janssen's "duty is fulfilled by giving adequate warning to the prescribing physician," not to Plaintiff. *Spensieri v. Lasky*, 723 N.E.2d at 549; ; *see also Lindsay*, 637 F.2d at 91 ("[T]he manufacturer's duty is to warn the doctor, not the patient."). As discussed further below, Plaintiff makes no allegation that the warnings Janssen provided were inadequate.

The Court also should dismiss Plaintiff's lack of informed consent with prejudice because any amendment would be futile. Amendment is futile when any "proposed amendments would not withstand a Rule 12(b)(6) motion to dismiss." *Lucente v. Int'l Bus. Machs. Corp.*, 310 F.3d 243, 258 (2d Cir. 2002). In other words, when a plaintiff cannot cure "pleading deficiencies" leave to amend should not be granted. *Scottrade, Inc. v. Broco Invs., Inc.*, 774 F. Supp. 2d 573, 584 (S.D.N.Y. 2011). Here, no matter what amendment Plaintiff makes to her informed consent claim, Janssen will never be a medical provider, and thus never will be subject to a lack of informed consent claim. Accordingly, Plaintiff's lack of informed consent claim should be dismissed with prejudice.

II. PLAINTIFF DOES NOT STATE A CLAIM FOR FAILURE TO WARN

Plaintiff's failure-to-warn claim also fails as a matter of law. To succeed on a failure-to-warn claim, Plaintiff must show that "(1) [Janssen] did not provide [her] physicians

with adequate warnings about risks that it knew or should have known [Invega®] cause; and (2) the inadequacy of those warnings was the proximate cause of [her] injuries." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). Thus, a "failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating *how* the provided warnings were inadequate." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012) (emphasis added). In fact, courts in this district routinely dismiss pharmaceutical product liability failure-to-warn claims when the complaint does not plead how a medicine's provided warnings were inadequate. *See e.g., Trisvan v. Heyman*, 305 F. Supp. 3d 381, 399 (E.D.N.Y. 2018) ("Plaintiff fails to provide any non-conclusory allegations to suggest that his treating physicians were not informed of the potential side-effects of Risperdral [sic] and Wellbutrin of which he complains."); *Surdo v. Stamina Prod., Inc.*, No. 15-CV-2532, 2015 WL 5918318, at *5 (E.D.N.Y. Oct. 9, 2015) ("However, Surdo does not plead that the defendants had a duty to warn; he does not specify the danger he was not warned about; and he does not describe how the failure to warn resulted in his injuries. Furthermore, he fails to plead facts stating how the provided warnings were inadequate, further warranting dismissal of the claim."); *accord Reed*, 839 F. Supp. 2d. at 575.

A. Plaintiff's Failure-to-Warn Claim Fails Because Plaintiff Makes No Plausible Allegation That The Invega® Label Was Inadequate

Plaintiff's complaint does not delineate any risk about which Janssen failed to warn about. Plaintiff's complaint also does not include any facts indicating "how the provided warnings were inadequate." *Id.* Indeed, Plaintiff's complaint does not include *any* allegations related to Invega®'s warnings at all. Plaintiff's allegations "do not include any factual content regarding what the misrepresentations were or how the provided warnings and information failed to 'accurately reflect' reality. *Id.* at 576. Furthermore, under the learned intermediary doctrine,

it is immaterial whether the Invega® warnings at issue adequately apprised Plaintiff, or any other consumer, of potential risks, or whether Plaintiff was actually provided such warnings. *Id.*; *see also Trisvan*, 305 F. Supp. 3d at 399 (dismissing action when "Plaintiff's chief complaint is that *he* was never informed about the risks by his treating physicians."). Instead, Plaintiff must plausibly allege facts showing that the warnings provided *to her physician* were inadequate.

Plaintiff cannot satisfy that standard by conclusory allegations that a warning was inadequate. On this point, *Reed* is instructive. In that case, the plaintiff alleged that "the drug was not accompanied by adequate warnings," "the drug was promoted without sufficient disclosure of its dangerous propensities," and "warnings and information . . . did not accurately reflect the symptoms, duration, scope, or severity of the potential side effects, health concerns, and risks." *Reed*, 839 F. Supp. 2d at 576. The court found such "allegations are simply not 'enough to raise a right to relief above the speculative level.'" *Id.* (quoting *Twombly*, 550 U.S. at 555). Similarly, in *Baily v. Janssen Pharmceutica, Inc.,* the plaintiff alleged in "only one conclusory sentence" that the drug at issue was "not accompanied by adequate instructions and/or warnings to fully apprise the prescribing physicians . . . of the full nature and extent of the risks and side effects associated with its use." 288 F. App'x 597, 608 (11th Cir. 2008). The Eleventh Circuit affirmed dismissal of the failure-to-warn claim because "[n]owhere does the complaint recite the contents of the warning label or the information available to [the prescribing] physician or otherwise describe the manner in which the warning was inadequate." *Id.* at 609.

Plaintiff's allegations here are even more threadbare than the claims that were dismissed in *Reed* and *Bailey*. Here, Plaintiff does not make *any* allegations about the warnings her physician received and thus, her failure-to-warn claim must be dismissed.

Plaintiff's complaint in *Gioia I* and an affidavit that Plaintiff filed in state court and later included in a letter filed in *Gioia II*, does list a number of purported side-effects including hypothyroidism, nerve damage, motor and vocal tics, confusion, hypertension, diabetes, and stroke. *Gioia I*, Compl. at 6-7; *Gioia II*, ECF Dkt. No. 15 at 29. However, Plaintiff has not made any allegations that suggest Janssen should have and did not warn of these side-effects or that Janssen's warnings were inadequate. As courts in this district have recognized, merely suffering from a side-effect does not create a cognizable failure-to-warn claim. *Reed*, 839 F. Supp. 2d. at 576-77 ("[T]hat Ms. Reed suffered from certain conditions . . . cannot alone make plausible a claim that defendants misrepresented or hid those risks in some way.").

Plaintiff's failure-to-warn claim must be dismissed because the complaint does not contain "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570.

B. Plaintiff's Failure-to-Warn Claim Fails Because Janssen Warned Of The Side-Effects Plaintiff Claims To Have Experienced

Plaintiff's failure-to-warn claim also must be dismissed because the FDA approved package insert warned of the side-effects that Plaintiff claims to have suffered. *See supra* at 2-3 (discussing the Invega® package insert and Plaintiff's claimed side-effects). Under New York law, a prescription medicine's warnings are deemed adequate when "information regarding 'the precise malady incurred' was communicated in the prescribing information." *Alston*, 670 F. Supp. 2d at 284. Following that principle, courts in this circuit dismiss failure-to-warn claims when the record reveals that the side-effects alleged are included in the medicines

package insert. *See, e.g.*, *Chandler v. Janssen Pharm.*, Inc., 322 F. Supp. 3d 314, 324 (E.D.N.Y. 2018) (collecting cases dismissing claims when manufacturer warned of alleged side effect); *Alston*, 670 F. Supp. 2d at 284 (same); *Trisvan v. Heyman*, No. 16-CV-00084 (MKB), 2018 WL 6573434, at *4–5 (E.D.N.Y. Dec. 13, 2018) (granting motion to dismiss when complained of side-effects were included in warnings). As discussed above, Plaintiff alleges that she suffered from motor and vocal tics, hypertension, diabetes, and stroke. *See supra* at 2-3. Each of these are side effects that were included in the original FDA approved package insert for Invega®. *Id.* Accordingly, under well-settled law, Plaintiff's claims must be dismissed because Janssen warned of "the precise malady incurred." *Alston*, 670 F. Supp. 2d at 284; *see also Trisvan*, 2018 WL 6573434, at *4–5 (taking judicial notice of warnings and dismissing complaint when defendant warned of alleged side-effects).

CONCLUSION

In light of the foregoing, Janssen respectfully requests that its motion be granted, and that Plaintiff's complaint be dismissed.

Dated: January 31, 2020
New York, New York

Respectfully submitted,

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